UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

IN RE LIPOCINE INC. SECURITIES LITIGATION	Civ. Action No.: 2:17-cv-00182-DB
This Document Relates To: All Actions	AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS JURY TRIAL DEMANDED

Lead Plaintiff Lipocine Investor Group ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Lipocine Inc. ("Lipocine" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Lipocine securities between

June 30, 2015 and June 28, 2016, both dates inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b5 promulgated thereunder, against the Company and certain of its officers and/or directors.

2. LPCN 1021, branded as TLANDO, is an oral testosterone replacement therapy designed for twice a day dosing. It is also the lead product candidate for Lipocine, a small tight knit company which does not have any Food and Drug Administration approved drugs currently on the market. Throughout the Class Period, Defendants touted the Phase 3 clinical trial results for LPCN 1021 both in terms of efficacy and safety. However, they failed to reveal that the trial results were based on a dosing scheme used for LPCN 1021 during the clinical trial ***that differed significantly*** from the dosing scheme the Company proposed to use in real world clinical practice, as described in Lipocine's New Drug Application to the Food and Drug Administration.

3. As a result of this glaring deficiency in the New Drug Application, on June 29, 2016 the Company announced that it received a Complete Response Letter for LPCN 1021 from the FDA, stating its application cannot be approved in its present form due to "***deficiencies related to the dosing algorithm for the label. Specifically, the proposed titration scheme for clinical practice was significantly different from the titration scheme used in the Phase 3 trial leading to discordance in titration decisions between the Phase 3 trial and real-world clinical practice.***"

4. The market, blindsided, sent shares of Lipocine plummeting $3.17 per share or over 50% to close at $3.10 per share on June 29, 2016, damaging investors.

JURISDICTION AND VENUE

5. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b5 promulgated thereunder by the SEC (17 C.F.R. §240.10b5).

3. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

4. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Defendants conduct business and operate within this District and a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the certification attached to its lead plaintiff motion, purchased Lipocine securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

7. Defendant Lipocine is a specialty pharmaceutical company, which develops pharmaceutical products using its oral drug delivery technology in the areas of men's and women's health. The Company is a Delaware corporation with offices in Lawrenceville, New Jersey. Lipocine's securities trade on the NASDAQ under the ticker symbol "LPCN."

8. Defendant Mahesh V. Patel ("Patel") has been the President and Chief Executive Officer ("CEO") of Lipocine throughout the Class Period.

9. Defendant Morgan R. Brown ("Brown") has been the Executive Vice President and Chief Financial Officer of Lipocine throughout the Class Period.

10. Defendants Patel and Brown are sometimes referred to herein as the "Individual Defendants."

11. Defendant Lipocine and the Individual Defendants are referred to herein, collectively, as the "Defendants."

12. Each of the Individual Defendants:

a. directly participated in the management of the Company;

b. was directly involved in the day-to-day operations of the Company at the highest levels;

c. was privy to confidential proprietary information concerning the Company and its business and operations;

d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

e. was directly or indirectly involved in the oversight or implementation of the Company's disclosure and procedure controls;

f. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

g. approved or ratified these statements in violation of the federal securities laws.

13. Lipocine is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

14. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Lipocine under *respondeat superior* and agency principles.

SUBSTANTIVE ALLEGATIONS

Background

15. Lipocine describes itself in its SEC filings as a specialty pharmaceutical company focused on applying its oral drug delivery technology for the development of pharmaceutical products in the area of men's and women's health.

16. The Company does not have any U.S. Food and Drug Administration ("FDA") approved drugs on the market. Its self-described "lead product candidate" is LPCN 1021, an oral testosterone replacement therapy designed for twice a day dosing. The only other two drugs in its portfolio during the Class Period were LPCN 1111 and LPCN 1107, both of which lagged far behind LPCN 1020 in the FDA regulatory approval process.

17. Lipocine is a small company. Based on information provided by the Company in its Class Period SEC filings, it only had between 17-25 employees throughout the Class Period. Only half of the employees "are engaged in drug development activities," with the remainder engaged "in general, administration. marketing and sales functions."

18. Lipocine explains in its SEC filings that:

> To date, we have funded our operations primarily through the sale of equity securities and convertible debt and through up-front payments, research funding and milestone payments from our license and collaboration arrangements. ***We have not generated any revenues from product sales and we do not expect to***

> ***generate revenue from product sales unless and until we obtain regulatory approval of LPCN 1021 or other products.***

Emphasis added.

The FDA Approval Process for LPCN 1021

13. Before the Company can market LPCN 1021 in the United States, it has to obtain FDA approval of the drug and apparatus under a §505(b)(2) New Drug Application ("NDA").

14. The FDA requires rigorous scientific testing to ensure that a drug is safe and effective for its intended use before the FDA will permit it to be marketed in the United States. Before considering approval of a drug for its indicated use, the FDA requires a "sponsor" to submit a NDA for consideration, which contains data from clinical trials, preclinical studies, and manufacturing information that supports the product's safety and efficacy. 21 U.S.C. 355(b); 21 CFR 314.50(d).

15. Clinical testing typically involves a three-phase process. The third and final phase in the process, known as Phase 3, is a large scale, multicenter, well-controlled clinical trial conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product for approval, as required by the FDA, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. INC Research was responsible for administering the Phase 3 study and overseeing the clinical trial sites for Lipocine.

16. All subjects that were randomized to receive LPCN 1021 during the Phase 3 trial were initially started at 225 mg testosterone undecanoate (TU) twice daily, which is equivalent to approximately 142 mg of testosterone twice daily. If needed, the dose was titrated up to 300 mg TU twice daily or down to 150 mg TU twice daily, and was dependent on serum testosterone levels measured during week 3 and week 7. "Titration" is the process of gradually adjusting the dose of a medication until optimal results are reached. The aforementioned titration scheme for

LPCN 1021 used during Phase 3 did not match the titration scheme for which Lipocine requested FDA approval per its NDA. In other words, any efficacy or safety information gleaned from the Phase 3 trial data did not take into account the way the drug would actually be used in real world practice.

Confidential Witnesses

17. Confidential Witness ("CW") 1 worked as a "Scientist III" for Lipocine at the Company's headquarters in Salt Lake City, UT from June 2008 through July 2016. As a Scientist III, CW1 worked in the Lipocine lab to support the research and production of the Company's products. In that role, among other things, CW1 coordinated with a senior scientist and a formulation scientist to get each product from the idea stage to proof of concept and then to clinical trial. CW1 performed many analyses and tests in support of the company's research, including research related to LPCN 1021. CW1 reported to Vice President of Product Development Chidu (Nachiappan) Chidambaram who reported directly to CEO Mahesh Patel.

18. CW1 made clear that everyone at the Company's Salt Lake City, UT headquarters was involved with the LPCN 1021 in one way or another. CW1s boss and the other Vice Presidents reported regularly to CEO Patel and CFO Brown in private meetings. CW1's boss in particular met with Defendant Patel regulatory about Company business. CW1 also stated that Defendants Patel and Brown certainly monitored the results of the SOAR study, particularly given the size of the Company.

19. CW2 worked as an Executive Director of Portfolio and Project Management for Lipocine from September 2014 through December 2015 and was based at the Company's headquarters in Salt Lake City. CW2 reported to Defendant Brown, but worked closely with

both Defendant Brown and Defendant Patel. CW2 stated that Defendants Patel and Brown were "very involved" in the Phase 3 trial conduct and results.

Materially False and Misleading Statements

20. On June 29, 2015, the Company issued a press release during after-market hours announcing the results of its Study of Oral Androgen Replacement pivotal Phase 3 clinical study evaluating the efficacy and safety of LPCN 1021, which stated in part:

> **Lipocine's Oral Testosterone Well Tolerated in Phase 3 Study**
> - LPCN 1021 was well tolerated during 52 weeks of dosing
> - No reported hepatic, cardiac or drug-related serious adverse events ("SAEs")
> - Overall adverse event ("AE") profile for LPCN 1021 was comparable to the active control, Androgel® 1.62%
>
> SALT LAKE CITY, June 29, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced top-line 52-week safety results from its Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021, an oral testosterone product candidate, in hypogonadal men with low testosterone. Overall, LPCN 1021 was well tolerated with no hepatic, cardiac or drug-related SAE's reported.
>
> Lipocine announced positive top-line efficacy results from the SOAR study in September 2014. ***The company still expects to file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") in the second half of 2015.***
>
> "We are pleased with the safety profile demonstrated by LPCN 1021. We believe that the efficacy and safety data from the SOAR study reinforces our understanding that LPCN 1021 represents a 'bestin-class' testosterone replacement therapy ("TRT") option with the potential to both improve treatment compliance and overcome inadvertent testosterone transference risk to children and partners," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "***We look forward to bringing this important new medicine to patients as we continue to work diligently on filing the NDA.***"
>
> SOAR is a randomized, parallel-group, active-controlled, open-label Phase 3 clinical study of oral TRT in hypogonadal males with low

> testosterone (< 300 ng/dL). In total, 315 subjects at 40 sites were randomized, such that 210 were randomized to LPCN 1021 and 105 were randomized to active control, for 52 weeks of treatment. Efficacy and safety were evaluated during the initial 13 weeks of the study and subjects continued to receive treatment through 52 weeks during a safety extension phase. ***All subjects randomized to LPCN 1021 were started at 225 mg testosterone undecanoate ("TU") (equivalent to ~ 142 mg of testosterone) twice daily ("BID") and then dose titrated, if needed, up to 300 mg TU BID or down to 150 mg TU BID. Dose titration decisions were based on serum testosterone levels measured during weeks 3 and 7.***

(Emphases added).

21. The foregoing statements were false and misleading because the Company failed to disclose that the reported results from the Phase 3 clinical trial, including information regarding efficacy, safety, and serious adverse events ("SAEs"), related to a titration scheme that differed significantly from the proposed titration scheme for clinical practice thus creating a substantial risk that the FDA would reject the LPCN 1021 NDA.

22. On August 11, 2015, the Company filed a Form 10-Q with the SEC for the quarter ended June 30, 2015 ("2Q 2015 10-Q"), which was signed by Defendants Patel and Brown. The 2Q 2015 10-Q stated in relevant part:

> Our lead product candidate, LPCN 1021, is an oral testosterone replacement therapy ("TRT") designed for convenient twice-a-day dosing that has completed Phase 3 testing, demonstrating positive top-line efficacy and safety results, and was well tolerated during 52 weeks of treatment.

The 2Q 2015 10-Q contained a detailed overview of the Phase 3 trial results for LPCN 1021, and also raised the issue of titration, but once again failed to mention that the titration scheme differed significantly from the proposed titration scheme for clinical practice. The 2Q 2015 10-Q stated in relevant part:

> *Top Line Results From SOAR*
>
> We recently completed our Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study evaluating efficacy and safety of LPCN 1021 and have received top-line efficacy results and 52-week top-line safety results. SOAR

is a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of oral TRT in hypogonadal males with low testosterone (< 300 ng/dL). In total, 315 subjects at 40 active sites were assigned, such that 210 were randomized to LPCN 1021 and 105 were randomized to the active control, for 52 weeks of treatment. The active control is included for safety assessment. ***LPCN 1021 subjects were started at 225 mg TU (equivalent to ~ 142 mg of T) twice daily ("BID") with a standard meal and then dose titrated, if needed, up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone measured during weeks 3 and 7.*** The mean age of the subjects in the trial is ~53 yrs with ~91% of the patients < 65 yrs of age.

Primary statistical analysis was conducted using the Efficacy Population Set ("EPS"). The EPS is defined as subjects randomized into the study with at least one PK profile and no significant protocol deviations and includes imputed missing data by last observation carried forward, N=152. Further analysis was performed using the full analysis set ("FAS") (any subject randomized into the study with at least one post-baseline efficacy variable response, N=192) and the safety set ("SS") (any subject that was randomized into the study and took at least one dose, N=210).

Efficacy

The primary efficacy end point is the percentage of subjects with an average 24 hour serum testosterone concentration ("Cavg") within the normal range, which is defined as 300-1140 ng/dL, after 13 weeks of treatment. The FDA guidelines for primary efficacy success is that at least 75% of the subjects on active treatment achieve a testosterone Cavg within the normal range; and the lower bound of the 95% confidence interval ("CI") must be greater than or equal to 65%.

LPCN 1021 successfully met the FDA primary efficacy guideline. In the EPS analysis, 88% of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82%. Additionally, sensitivity analysis using the FAS and SS reaffirmed the finding that LPCN 1021 successfully met the FDA primary efficacy guideline as 88% and 80%, respectively, of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82% and 74%, respectively.

Other top-line highlights from the efficacy results include:

· Mean Cavg was 447 ng/dL with coefficient of variance of 37%;

· Less than 12% of the subjects were outside the tesosterone Cavg normal range at final dose;

· ***85% of subjects arrived at final dose with no more than one titration; and***

· 51% of subjects were on final dose of 225 mg BID which was also the starting dose.

In the EPS analysis, Cmax ≤1500 ng/dL was 83%, Cmax between 1800 and 2500 ng/dL was 4.6% and Cmax > 2500 ng/dL was 2%. Three patients had a Cmax >2500 ng/dL which were transient, isolated and sporadic. Moreover, none of these subjects reported any adverse events, or AE's. Results were generally consistent with those of approved TRT products.

Safety

The safety component of the SOAR trial was completed the last week of April 2015. The safety extension phase was designed to assess safety based on information such as metabolites, biomarkers, laboratory values, serious adverse events, or SAEs, and AEs, with subjects on their stable dose regimen in both the treatment arm and the active control arm. LPCN 1021 treatment was well tolerated in that there were no hepatic, cardiac or drug related serious adverse events.

Top-line LPCN 1021 safety highlights include:

· LPCN 1021 was well tolerated during 52 weeks of dosing;
· Overall AE profile for LPCN 1021 was comparable to the active control, Androgel® 1.62%;
· The only AEs occurring in more than 5% of subjects with either LPCN 1021 or the active control were upper respiratory tract infection (5.2% with LPCN 1021 and 5.8% with active control) and fatigue (2.4% with LPCN 1021 and 6.7% with active control);
· Cardiac AE profiles were consistent between treatment groups and none of the observed cardiac AEs occurred in greater than 1.0% of the subjects in the LPCN 1021 arm and none were classified as severe;
· Drug-related AEs, or ADRs, occurring in more than 2% of subjects with either LPCN 1021 or active control were headache (0.5% with LPCN 1021 and 3.9% with active control), acne (2.9% with LPCN 1021 and 2.9% with active control) and patient reported perceived weight increase (2.4% with LPCN 1021 and 0% with active control);
· The overall mean weight change as compared to baseline was not significantly different between the treatment groups (Weight changes greater than 10% from baseline over 52 weeks occurred in 2.3% of subjects with LPCN 1021 and 3.8% of subjects with the active control);
· All observed ADRs were classified as mild or moderate in severity and no serious ADRs occurred during the 52-week treatment period;
· ADRs, such as peripheral edema, polycythemia, and thrombocytopenia, occurred in 1% or fewer subjects with LPCN 1021;

> · There were no significant changes in mean systolic and diastolic blood pressure from baseline in either treatment arm;
> · Mean values for the lipid parameters, except high density lipoprotein levels ("HDL"), were not significantly different from baseline;
> · Mean HDL levels following LPCN 1021 treatment decreased slightly from baseline but were not significantly different from the active control after 52 weeks of exposure;
> · Mean values for cardio biomarkers were not significantly different from baseline;
> · Mean values for liver enzymes remained within the normal range;
> · Mean values for hematocrit, hemoglobin, platelet count, prothrombin time and prostate specific antigen, were not significantly different from baseline; and
> · Mean dihydrotestosterone levels increased from baseline following LPCN 1021 treatment, but were comparable to changes seen with the active control.

Defendants also discussed the status of the NDA approval process without revealing the deficiencies with the NDA, *i.e.*, the titration scheme discrepancy, which created a risk that the Company would ultimately receive a Complete Response Letter from the FDA:

> On March 19, 2015, we had our pre-NDA meeting with the FDA. The purpose of the meeting was to discuss and obtain concurrence regarding adequacy for submission of the proposed NDA package for LPCN 1021 and to receive guidance on the 505(b) (2) filing and approval. ***Based on the FDA's preliminary response, we do not expect to conduct any additional clinical studies other than the labeling "food effect" study which was completed in May 2015.*** Top-line results from the labeling "food effect" study indicate that bioavailability of testosterone from LPCN 1021 is not affected by changes in meal fat content. The results demonstrate comparable testosterone levels between the standard fat meal (similar to the meal instruction provided in the Phase 3 clinical study) and both the low and high fat meals. The labeling "food effect" study was conducted per the FDA requirement and we submitted preliminary results from this study to the FDA in the second quarter of 2015 prior to submitting the NDA. Based on our meeting with the FDA, we do not expect to be required to conduct a heart attack and stroke risk study or any additional safety studies prior to filing the NDA for LPCN 1021. Additionally, prior to our pre-NDA meeting with the FDA, the FDA highlighted the need to ensure our efficacy data was robust to sensitivity analyses with various data sets, including the FAS. We expect an NDA filing to occur during the second half of 2015.

23. The foregoing statements were misleading for the reasons set forth in paragraph 21.

24. The same day, the Company issued a press release, which stated in relevant part:

> Completed an underwritten public offering of 5,347,500 shares of its common stock at $6.50 per share for gross proceeds of $34.8 million. Lipocine received net proceeds of approximately $32.4 million, after deducting the underwriters' discounts and other estimated offering expenses.

25. While raising this money, the Company did not disclose that prospects for its lead drug candidate were questionable given the divergent titration schemes between Phase 3 trial practice and intended real world clinical practice.

26. On August 31, 2015, the Company issued a press release announcing its submission of a New Drug Application ("NDA") for LPCN 1021 to the U.S. Food and Drug Administration's ("FDA"), which states in part:

> **Lipocine Submits New Drug Application to FDA for Its Oral Testosterone Replacement Product Candidate, LPCN 1021**
>
> SALT LAKE CITY, Aug. 31, 2015 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that it has submitted a 505(b)(2) New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for LPCN 1021, an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone ("hypogonadism").
>
> "Filing of the NDA for LPCN 1021 is a significant achievement for Lipocine and a major milestone toward bringing this potential testosterone replacement therapy option to patients. LPCN 1021 has the potential both to improve the ease of use compared to the available formulations, including topical gels and injections, and to overcome inadvertent testosterone transference risk to children and partners," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We look forward to working closely with the FDA during the review process."
>
> The NDA filing is supported by results from Lipocine's Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021 in hypogonadal men with low testosterone. The study met its primary efficacy endpoint by successfully restoring testosterone levels to the normal range in 88% of the subjects. ***In addition, 85% of the subjects reached their final dose with no more than one dose titration. LPCN 1021 treatment was well tolerated with no hepatic, cardiac, gastrointestinal or drug related serious adverse events***.

(Emphases added).

27. The foregoing statements were misleading for the reasons set forth in paragraph 21.

28. On October 29, 2015, the Company issued a press release announcing the FDA's acceptance of the Company's NDA for LPCN 1021, which stated in part:

> **FDA Accepts for Filing Lipocine's New Drug Application for Its Oral Testosterone Replacement Product Candidate, LPCN 1021**
>
> SALT LAKE CITY, Oct. 29, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing its New Drug Application ("NDA") for LPCN 1021, an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone ("hypogonadism"). The acceptance by the FDA of the NDA indicates that the application is sufficiently complete to permit a substantive review.
>
> "FDA acceptance of the NDA for LPCN 1021 is a significant milestone for both Lipocine and the millions of patients that could potentially benefit from an oral testosterone replacement therapy option," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We will continue to work with the FDA as they complete their review."

29. The foregoing statements were misleading for the reasons set forth in paragraph 21.

30. On November 12, 2015, the Company filed its quarterly report for the quarterly period ended September 30, 2015 on Form 10-Q with the SEC (the "3Q 2015 10-Q"). The 3Q 2015 10-Q was signed by Defendants Patel and Brown. The 3Q 2015 10-Q reiterated all the same information regarding LPCN 1021 and the Phase 3 trial results set forth herein in paragraph 22. The 3Q2015 10-Q also stated, in relevant part:

> The FDA accepted our NDA in October 2015 and has assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 28, 2016 for completion of the review. Additionally, the 74-day filing communication letter did not mention a need to convene an Advisory Committee for advice on the NDA for LPCN 1021.

31. The foregoing statements were misleading for the reasons set forth in paragraph 21.

32. On March 10, 2016, the Company filed its annual report for the fiscal year ended December 31, 2015 on Form 10-K with the SEC (the "2015 10-K"). The 2015 10-K was signed by Defendants Patel and Brown. The 2015 10-K reiterated all of the same misleading statements set forth in paragraphs 22 and 30 herein.

33. The foregoing statements were misleading for the reasons set forth in paragraph 21.

34. On April 13, 2016, the Company presented at the 15th Annual Needham Healthcare Conference. Slide 16 of the presentation covered the number of dose titrations required for LPCN 1021 during the Phase 3 trial as compared to alternative competitor products. During that presentation, Defendant Patel stated as follows:

> I am here to convince you to become part of Lipocine because it is such a great opportunity and here is the reason why.
> First of all, we are very close to a huge value driving event so we are just a little over 10 weeks away from PUDFA date of our lead asset and we believe it is a great opportunity because we got first innovative oral testosterone which has remained elusive for quite a while and I will go through the data.
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> ***
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> I am (inaudible) first because a couple of competitors ran into problems with regards to approval so we believe we are right now the leader in the space. And I will make a case why we have a differentiated product and the product is targeting a $2 billion market. In dollar terms, it is stable, it is a robust, it is healthy.
>
> ***
>
> And like I mentioned, we would have the first entrant advantage of being the first oral. More importantly, we believe we have robust clinical data and we also have a branded market leader, the current market leader we had in our pivotal study as an active control. So we have a good set of data.
>
> ***

So let me make a case on our lead asset, why we believe it is differentiated. First of all, the NDA was accepted in October of last year. And for clarity what we are targeting is a class TRT label so testosterone replacement label. What that means is that our regulatory paradigm is well-defined and we will be accorded the same benefit of other non-oral products that were approved. I know there's a lot of questions these days about what is the new paradigm? But we believe that if you stick to the class label and your safety profile is comparable or indistinguishable from the other TRT products on the market, getting approval of oral testosterone product should be I guess approved on the basis of the same regulatory paradigm.

***

Our efficacy is very robust. It is 87% compared to 75% requirement for FDA's primary endpoint. And as far as safety, we will probably be one of the only few products that would have a long-term 52-week exposure data at the time of approval. Our safety profile is well-tolerated. It is indistinguishable with the market leader that we had in our own study and including the GI effects, there were zero cardiac, hepatic or GI-related serious adverse events.

So again, indistinguishable in terms of safety, robust efficacy and we have a true differentiation and of course the black box warning, there is no propensity to accidental transference to women and children.

But more importantly we believe when we compare the market leader and our own study, we found that our starting dose is the right dose for most patients. Now this has got a lot of value in terms of for the patient. Most men don't like to go back to the doctor's office to get their dose adjusted. So the majority of men can be assured that they may not have to go back two or three times to get their dose adjusted. It is a better product.

***

Like I said our dose, starting dose, is the right dose for most patients. So these were some of the issues and we have addressed most of the issues in our NDA and therefore we are not surprised that they are not planning on having an advisory committee meeting. They indicated to us that there are not planning on having one. So that is our lead asset.

35. The foregoing statements were misleading for the reasons set forth in paragraph 21.

36. On May 9, 2016, the Company filed its quarterly report for the quarterly period ended March 31, 2016 on Form 10-Q with the SEC (the "1Q 2016 10-Q"). The 1Q 2016 10-Q

was signed by Defendants Patel and Brown. The 1Q 2016 10-Q reiterated all of the same misleading statements set forth in paragraphs 22 and 30 herein.

37. The statements referenced in ¶¶ 20 - 36 above were materially false and/or misleading because they misrepresented and failed to disclose that the Company's filing of its NDA for LPCN 1021 with the FDA contained deficiencies that raised a substantial risk that the Company would receive a Complete Response Letter declining to approve the NDA in its present form. The NDA's deficiencies, and resulting risks, were known to Defendants or recklessly disregarded by them throughout the Class Period.

The Truth Emerges

38. On June 29, 2016, the Company issued a press releasing disclosing its receipt of a Complete Response Letter for LPCN 1021 from the FDA, stating in relevant part:

> **Lipocine Receives Complete Response Letter (CRL) for LPCN 1021 From U.S. Food and Drug Administration**
>
> SALT LAKE CITY, June 29, 2016 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that it has received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA") for LPCN 1021, an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.
>
> ***The CRL identified deficiencies related to the dosing algorithm for the label. Specifically, the proposed titration scheme for clinical practice was significantly different from the titration scheme used in the Phase 3 trial leading to discordance in titration decisions between the Phase 3 trial and real-world clinical practice.***
>
> The next step will be to request a meeting with the FDA to understand more fully the issues raised and to agree on a path forward to achieve approval of LPCN 1021.

> "We are evaluating the content of the CRL, including the FDA recommended actions to bring our NDA in a position for approval, and will work closely with the FDA to determine the appropriate next steps for the NDA. We remain committed to bringing LPCN 1021 to patients who will benefit from its intended use," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "We continue to believe that LPCN 1021 has the potential to improve the ease of use compared to the available formulations, including topical gels and injections, and to overcome inadvertent testosterone transference risk to children and partners that exist with topical gels.

(Emphasis added).

39. On this news, shares of Lipocine fell $3.17 per share or over 50% to close at $3.10 per share on June 29, 2016, damaging investors.

40. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

41. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Lipocine securities trade on the NASDAQ during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

42. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Lipocine securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds

or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Lipocine or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

29. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

30. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

31. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Lipocine;
- whether the Individual Defendants caused Lipocine to issue false and misleading public statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading public statements;

- whether the prices of Lipocine securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and,
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

32. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

33. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudonthe-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Lipocine securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased and/or sold Lipocine securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

34. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

35. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Against All Defendants

36. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

37. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b5 promulgated thereunder by the SEC.

38. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances

under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Lipocine securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Lipocine securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

39. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Lipocine securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Lipocine's disclosure controls and procedures, business operations, and employee conduct.

40. By virtue of their positions at Lipocine, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant

knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

41. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Lipocine, the Individual Defendants had knowledge of the details of Lipocine's internal affairs.

42. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Lipocine. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Lipocine's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price for Lipocine's securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Lipocine's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Lipocine securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged upon the revelation of the alleged corrective disclosures.

43. During the Class Period, Lipocine's securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused

to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Lipocine securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Lipocine securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Lipocine's securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

44. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b5 promulgated thereunder.

45. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Violation of Section 20(a) of The Exchange Act Against The Individual Defendants

46. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

47. During the Class Period, the Individual Defendants participated in the operation and management of Lipocine, and conducted and participated, directly and indirectly, in the

conduct of Lipocine's business affairs. Because of their senior positions, they knew the adverse nonpublic information regarding Lipocine's business practices.

48. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Lipocine's financial condition and results of operations, and to correct promptly any public statements issued by Lipocine which had become materially false or misleading.

49. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Lipocine disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Lipocine to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Lipocine within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Lipocine securities.

50. Each of the Individual Defendants, therefore, acted as a controlling person of Lipocine. By reason of their senior management positions and/or being directors of Lipocine, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Lipocine to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Lipocine and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

51. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Lipocine.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: April 27, 2017

Respectfully submitted,

/s/ Tamar A. Weinrib

POMERANTZ LLP
Jeremy A. Lieberman
Tamar A. Weinrib (*pro hac vice*)
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
Email: jalieberman@pomlaw.com
taweinrib@pomlaw.com

POMERANTZ LLP
Patrick V. Dahlstrom
10 South La Salle Street, Suite 3505
Chicago, Illinois 60603
Telephone: (312) 377-1181
Facsimile: (312) 377-1184
Email: pdahlstrom@pomlaw.com

CHRISTENSEN YOUNG & ASSOCIATES
Zane L. Christensen (
9980 S 300 W STE 200
Sandy, Utah 84070
Telephone: (866)861-3333
Email:
zanechristensen@christensenyounglaw.com

Counsel for Lead Plaintiff and the Class